

K010526

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### 510(k) Summary

DEC 1 3 2001

September 27, 2001

#### SUBMITTER'S NAME AND ADDRESS

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#### NAME OF DEVICE

Trade Name:            "The Grip"

Common Name:        CPR Assistance Device

Classification Name: Aid, Cardiopulmonary Resuscitation

#### DEVICE CLASSIFICATION / CLASSIFICATION PANEL

The FDA DIVISION OF CARDIOVASCULAR, RESPIRATORY, AND  
NEUROLOGIC DEVICES has classified the "AID, Cardiopulmonary  
Resuscitation" device as an UNCLASSIFIED device pursuant to 21 C.F.R.

PANEL:                Cardiovascular

PRODUCT CODE:    **LIX**

PREDICATE DEVICE:            CPRplus      K926333

## INTENDED USE

"The Grip" is designed to assist a rescuer in performance of Cardiopulmonary Resuscitation (CPR).

## DEVICE DESCRIPTION / SUBSTANTIAL EQUIVALENCE

"The Grip" is composed of two parts which may be packaged and stored in a carrying case together.

The lower section is a disposable chest pad consisting of (a) a nearly rectangular 5" x 6" x 1/16" semirigid, flexible sheet of plastic such as ABS, Lexan, Plexiglas, or polypropylene, (b) a rectangular socket to receive the base of the upper section, 2-1/2" x 3-1/2" standing 3/4" tall with a rectangular cavity 2-1/16" x 3-1/16" which is 3/8" deep. And (c) the underside of the chest pad is padded with 1/8" thick closed cell plastic foam and a layer of 2-sided adhesive tape (3M # 9877) with a peel-off paper backing.

The reusable upper section is composed of (a) a hand grip of plastic which serves also as a battery compartment for the battery pack. The grip is 3-1/2" in diameter and 2-1/8" tall. The handgrip is shaped like a truncated inverted cone with a flattened curved upper surface which serves as a lid to the battery compartment. (b) the force sensor part is enclosed in a hollow rectangular plastic cover measuring 2" x 3" and 3/4" deep. The underside of the force sensor cover has four apertures at the four corners through which protrude cylindrical pegs. Rubber boots on the pegs provide water resistance. The pegs are affixed to the corners of a rectangular wobble plate inside the sensor box. When in use, this free-floating plate presses against the closed-top neoprene washer pad of a Motorola MPX-5100 pressure sensor component which forms a small air chamber over the port. Force applied by the wobble plate causes reduction in size of the air chamber with proportional increase in air pressure which is sensed by the sensor and transmitted to the electronic processor. Part of the display module also forms the upper covering of the sensor compartment. Four microswitches lie on the undersurface of the upper sensor cover and align with the edges of the wobble plate. The switches detect a tilting condition when force is misapplied along the axis of the handgrip [TILT monitor]. (c) The display panel module is hollow plastic. The display panel is composed of dome switches and LEDs embedded in plastic membrane with a shape like a stylized heart. The butt end is sandwiched between the handgrip and sensor compartment. Electrical wiring and printed circuits connects the various components. Two steel screws anchor the three sections together. The hollow end of the display section has a cover on its underside. Within the hollow is a circuit board to which are mounted electronic components. Interfaces are sealed with silicone RTV.

Switches and LEDs extend from the board through openings in the upper surface of the panel, or are embedded in the display panel membrane, to provide a compact array of controls and display lights. Switches can select on/off, metronome rate, stroke counter ratio, and counter reset. The LEDs are arrayed to indicate the metronome timing pulse, selected metronome rate, and tilting condition. A running light display indicates the approximate force applied to the chest. A two-digit counter displays the stroke count and automatically resets at a selected 15 or 5 count to remind the rescuer to give appropriate breaths during a rescue. The mid-position of the counter switch turns the stroke counter off. A piezo speaker is mounted in the display to provide

an audible tone for the metronome and stroke counter alarm. The TILT monitor and stroke counter are convenience features not found on the predicate device.

The company's device called "The Grip" covered by this submission is substantially equivalent to other legally marketed CPR assist device. Specifically, "The Grip" is substantially equivalent to the device called CPRplus. "The Grip" has the same general intended use, similar principles of operation, and similar technological characteristics as the previously cleared predicate CPRplus. "The Grip" and its predicate device are all intended for use by a rescuer to assist in performance of CPR. The predominately plastic devices are employed by placing on the chest of a victim of cardiac arrest in landmark location according to directions on the labeling. The rescuer's hands are placed upon the upper surface of the device with downward force subsequently being applied toward the lower half of the sternum. The sternum is depressed 1-1/2 to 2 inches in a rhythmic fashion and at intervals there is a brief pause to give a rescue breath to the victim. The devices both provide a metronome with audible and visual cues to prompt the rescuer to provide compressions at a rate recommended by the American Heart Association. The rate selector of both devices may be set for 80 or 100 strokes per minute. The recommended default rate is 80 per minute for both devices. The devices both report force applied by the rescuer so that one may maintain an adequate but not excessive compressive force on a victim's chest. The predicate device employs a manometric dial to display force and "The Grip" employs a running light display of LED's to display applied force. Force indicator increments (markings or LEDs) are similar for both devices, with 20 lb increments from 40 - 100 pounds. The desired range of 80 - 100 pounds of force (average adult) is indicated by dial markings of the predicate device and indicated by green colored LED's by "The Grip". Forces greater than 100 pounds are indicated by a red band on the dial of the predicate device and a red LED on "The Grip". The metronome of the predicate device is powered by a single 9 volt battery, and space is provided for a backup battery in the carrying case. The power for "The Grip" is provided by four AA batteries enclosed in a pack which is placed within the battery compartment of the handle. A spare battery pack is available in the carrying case. Replacement AA alkaline batteries are readily available in shops and stores. Replacement battery packs are available from electronic shops worldwide. The low battery indicator light of both devices warn of impending exhaustion of the battery, while still allowing adequate performance time to finish the present rescue. The predicate device incorporates a strip of rough sandpaper on its undersurface to reduce slippage during CPR, whereas "The Grip" utilizes a disposable chestpad which has removable adhesive on its underside to reduce the risk of slippage and maintain proper positioning. The adhesive is NOT designed or intended to be used for CPR employing the "compression-decompression" technique.

Features found on "The Grip" and absent from the predicate device include 1) a monitor of tilting (application of force in a direction different from the intended axis, ie. not straight downward), and 2) a stroke counter which may be set for 5 or 15 strokes prior to a warning chirp to remind the rescuer to give a rescue breath. The stroke counter may be turned off, if desired.

Although there are minor differences in the characteristics of "The Grip" and its predicate device, those differences do not raise new questions of safety or efficacy.

#### PERFORMANCE TESTING

Briefly, the sensor, as calibrated, was linear over its operational range of 40 - 100 pounds, with regard to force and voltage output (measured by a voltmeter, and by the LED display). The

metronome was accurate to within 1 beat per minute. The Tilt monitor switches lighted the appropriate LEDs when a tilting condition was intentionally created on the device at about 80 - 100 lbs of force. The battery pack lasted for over 100 hours when allowed to drive the metronome unattended. We estimate that the device can operate under actual conditions for multiple rescues before needing to change a battery pack. However, we recommend that the pack be refreshed after 3 - 4 uses, which is rarely over 60 minutes per rescue. The snap leads to the battery pack will also fit a standard 9 volt battery which could be used if AA batteries are temporarily unavailable, however, the 9 volt battery has a more limited life.

The device was found to perform normally when operated in a magnetic field or near a defibrillating current, and did not produce any significant electromagnetic interference at radio frequencies normally employed in hospitals or ambulances. The device was shock & water resistant as demonstrated by retaining its performance and accuracy after dropping a distance of 1 meter onto concrete and/or into water.

Results of trials employing simulated rescuers (5 EMT's and one trauma nurse) under static and moving-ambulance conditions showed that all six persons improved performance over bare-handed CPR when "The Grip" was employed to monitor performance in real time. The findings are similar to those of others who have reported that adequate CPR performance can be better sustained when a monitoring device is employed.

#### CONCLUSION

The device called "The Grip" is substantially equivalent to its predicate device called CPRplus.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 13 2001

Elroy Cantrell, D.O., Ph.D.  
Elcare Innovations, Inc.  
685 Elkins Lake  
Huntsville, TX 77340

Re: K010526  
The Grip  
Regulatory Class: Unclassified  
Product Code: 74 LIX  
Dated: September 27, 2001  
Received: September 28, 2001

Dear Dr. Cantrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

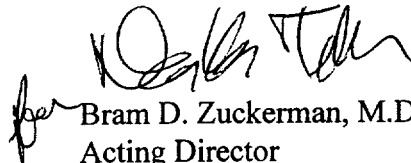
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.  
Acting Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K010526

Device Name: The Grip

Indications For Use:

To assist a rescuer in maintaining performance during  
application of CPR to a victim of cardiac arrest

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OK  
(Per 21 CFR 801.109)

OR

K. D. Tull  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K010526

Over-The-Counter Use X

(Optional Format 1-2-96)